REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments that follow. By this amendment, claim 16 is currently amended. Support for the claim amendments is found in the previously presented claims, and in the Examples. Upon entry of the present Response, Claims 16 – 17, 19 – 32 are pending and await further consideration on the merits.

Applicants first wish to thank the Examiner for withdrawing the double patenting rejection over U.S. Application No. 10/522,234.

REJECTIONS UNDER 35 U.S.C. § 112, 1ST PARAGRAPH

Claims 16, 17 and 19–31 are rejected under 35 U.S.C. § 112, 1st paragraph, as failing to comply with written description. Specifically, the Examiner states the new amendment to the claims of "coating film is between about 3% and about 7%" is not supported by the specification. Office Action at page 2. The Examiner notes that the specification recites at least 3%, and at least 5%. *Id.*

The specification supports the range of about 3% to about 7% because it has clear support in the Examples and Tables. For example, Table 1 and 2 show a formulation with about 3.2g coating and 50g granule core. *See*, [0168], [0179]. This yields about 6% by mass coating and 94% by mass granule core. *See*, *Id.* Table 3 shows a formulation with about 3.76g coating and 50g granule core. *See*, [0188]. This yields about 7% by mass coating and 93% by mass granule core. *See*, *Id.*

In all three of these examples, the formulations clearly state the "% by mass" of the compounds, with the granules being 94%, 94% and 93% (Table 1, 2 and 3, respectively) and the coating being about *6%*, *6%* and *7%* (Table 1, 2 and 3, respectively). As such, Applicants assert there is support for the claim amendment of a "coating film is between about 3% and about 7%." Applicants therefore request the rejection be withdrawn.

The Examiner also rejects Claims 16-17 and 19-32 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite because of the language "coating film is between *at least* about 3%..." Applicants have removed this language and therefore requests the rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102

The Applicants thank the Examiner for withdrawing the 35 U.S.C. § 102(b) rejection over Mehta (U.S. Patent 5,084,278) in light of the claim amendment. The Examiner has requested the Applicants show support for the claim amendment. As noted above, the specification contains support for the coating being at least 3%, and at least 5% weight to weight of the total microparticle mass. *See*, specification at [0157]. The specification also has support for the coating being 6% and 7% weight to weight of the total microparticle mass. *See*, Table 1, 2 and 3 at [0168], [0179] and [0188]. As such, Applicants assert the support for the claim amendment of a "coating film is between about 3% and about 7%" is found at [0035], [0157], [0168], [0179], [0188] and in original claim 1. Applicants therefore request the rejection be withdrawn.

REJECTION UNDER 35 U.S.C. § 103

Claims 16 – 17 and 19 – 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mehta (U.S. 5,084,278), in view of Mulye (U.S. 6,946,146).

The burden is on the Examiner to make a *prima facie* case of obviousness, which requires an objective analysis as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). In *KSR International v. Teleflex Inc.*, 127 S.Ct 1727, 82 USPQ2d 1385 (2007), the Court affirmed that this analysis includes the following factual inquiries: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. The Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 In View of the Supreme Court

Decision in *KSR International Co. v. Teleflex Inc.* state that, having undertaken the factual inquiries of *Graham*, a rejection under 35 U.S.C. § 103 may be supported by one or more of seven rationales. 72 Fed. Reg. 57526, at 57529 (October 10, 2007). Each of the rationales requires predictability in the art and/or a reasonable expectation of success, and the Examiner must consider objective evidence which rebuts such predictability and reasonable expectation of success. This objective evidence or secondary considerations may include unexpected results and/or failure of others (*e.g.*, evidence teaching away from the currently claimed invention), evidence of commercial success, and long-felt but unsolved needs, as found in the specification as-filed or other source. *Id.* When considering obviousness of a combination of known elements, the operative question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR* at 1740, 82 USPQ2d at 1396. Here, the Examiner has not met this burden.

Claim 16 is the basis of all claims under consideration. Claim 16 is to:

> Orally administered microcapsules for modified release of at least one active principle with low solubility,
> wherein the mean diameter of the microcapsules are less than 1000 microns;
> wherein each microcapsule has a core comprising at least one active principle and at least one solubilizing agent,
> wherein the at least one solubilizing agent increases the solubility of the at least one active principle by more than 50% when the at least one solubilizing agent is placed in an aqueous solution at a concentration of 20% w/w at 37°C;
> wherein the at least one solubilizing agent confers properties upon the core such that in a dissolving test (TD) a non-coated core releases 80% of the at least one active principle in less than two hours;
> wherein the core is coated with a coating film which controls the modified release of the active principles;
> wherein the coating film is between about 3% and about 7% dry weight/dry weight of the microcapsule mass;
> wherein the coating film of each microcapsule comprises at least one film-forming polymer (P1) insoluble in gastrointestinal tract fluids, at least one water-soluble polymer (P2), and at least one plasticizer, (PL).

1) Neither Mehta nor Mulye teach a coating film of about 3% to about 7% dry weight/dry weight of the microcapsule mass

The Examiner alleges that Mehta teaches about 7% because Mehta teaches a coating comprising 5% high temperature film forming polymer and about 5% low temperature film forming polymer "based on the total weight of polymer in the microcapsule coating." Office Action at page 4-6. The Examiner appears to add the two polymer percentages, and states the use of about in the "disclosed amount of 10%" results in "a very close and obvious overlapping percentages." *Id.* at page 8. Applicants disagree, first about 10% does not overlap about 7% but more importantly, the Examiner misreads the claim requirements and misreads Mehta's teaching.

Claim 16 requires that the coating film be between about 3% and 7% dry weight/dry weight of the microcapsule mass. Thus, as shown in Table 1, the claimed three coating components P1+P2+PL equals 100% of the coating. The coating as a whole is about 3% to 7% of the weight of the entire microcapsule.

Table 1: Claim 16

P1 + P2 + PL = 100% of coating		
	Low range	High range
Coating (P1+P2+PL)	3%	7%
Remainder of microcapsule	97%	93%

In contrast, Mehta teaches that the coating is a mixture of at least 5% high temperature film forming polymer (HT), and at least 5% low temperature film forming polymer (LT) "based on the total weight of the polymer in the microcapsule coating." *See*, Mehta at Col. 4, ll. 24-31.

Table 2: Mehta

Low temp polymer (≥5%) + High temper polymer (≥5%) + Other polymers (≤90%) Other excipients (N/A) = 100% of coating		
	Low range	High range
Coating	20%	40%
Remainder of the microcapsule	80%	60%

Thus, HT+LT+ other polymers equals 100% of the coating. The Mehta citation the Examiner refers to ***does not teach*** percentage coating weight/dry weight of the ***microcapsule mass***. Instead, the Mehta teaching is percentage "based on total weight of the polymer in the ***microcapsule coating***." *Id.* (emphasis added).

The only time Mehta does teach a coating percentage based on weight/dry weight of the microcapsule, the percentage is 20 – 40% (Col 10, ll. 30 – 21, 63 – 65). EudragitL30D, Eudragit L30D, Eudragit E30D, Eudragit NE30D and Aquacoat are liquids containing 30% of dry substance. Therefore, coating percentage of example 1 in Mehta is calculated as follows: Coating Percentage = (4*0.3)*100/(4+4*0.3) = 23%. The coating percentage exemplified in examples 1 and 3 is 23% (Col. 11, ll. 5-12, 45-50), far outside of the claimed range of about 3% to 7%. Further, Mulye does not teach a coating film percentage dry weight/dry weight of the microcapsule mass and cannot correct this deficiency. Nothing in either reference would teach or suggest such a percentage requirement, and thus the claimed invention cannot be obvious over the combination of these references.

2) **One of skill in the art would not form a coating film of about 3% to about 7% dry weight/dry weight of the microcapsule mass based on the teaching of Mehta because Mehta is to taste masking**

As noted above, Mehta in no way teaches about 3% to 7% and instead teaches that the coating is 20 – 40% (Col 10, ll. 30 – 21, 63 – 65) or by weight of the microcapsules. Mehta is

directed to compositions that mask taste so the drug, when chewed, does not produce a bitter taste. *See*, Mehta at Col. 1, ll. 6 – 8. The purpose of making such a composition is to increase patient compliance, especially for children who may chew the pharmaceutical. *Id.* at Col. 1, ll. 32 – 46.

The higher range of coating for Mehta is logical and expected, because it is more likely that a thicker coating (20 – 40%) would mask taste as opposed to a thinner coating. According to Fick's first law of diffusion, the diffusion flux (or rate of transfer) is inversely proportional to the distance x (thickness).

$$J = -D\frac{\partial \phi}{\partial x}$$

Thus, a thicker coat would decrease diffusion flux, and less bitter-tasking drug is released. For this reason, to reach a goal of prolonging the release of poorly soluble drugs, as in the present invention, one of skill in the art would not think to apply a thicker coat because a thick coat composed of barrier polymers would result in absence of release.

Further, Mulye has no teaching on the coating film weight/weight microcapsule, much less the very small amount of about 3% to about 7%, as required by the claims. One of skill in the art therefore would not modify Mehta, alone or in combination with Mulye, to *prolong the release of poorly soluble drugs.*

3) One of skill in the art would not form the very specific coating film of P1+P2+PL based on the teachings of Mehta and Mulye

The film-forming polymer (P1), which is insoluble in gastrointestinal tract fluids, and the water-soluble polymer (P2) of the claimed invention do not correspond to the high temperature film forming polymer and the low temperature film forming polymer of Mehta. In the high temperature film forming polymers according to Mehta, one can find ethylcellulose which is also a polymer P1 of the invention, but no polymer corresponding to P2 can be found in the coating of Mehta. P2 belongs to the group of: water-soluble derivatives of cellulose, polyacrylamides, poly-N-vinylamides, poly (N-vinyl lactams), polyvinyl alcohols, polyoxyethylenes, and

polyvinylpyrrolidones; whereas low temperature film forming polymers of Mehta are copolymers of methacrylic acid esters (Eudragit E30D, Janocryl 77 and Eudragit E100) (Col. 5, l. 66 to Col. 6, l. 6). Mehta does not disclose polyvinylpyrrolidone in the coating but a different compound vinyl pyrrolidone (Col. 5, l. 49) (See below paragraph 4 for further discussion of the differences between polyvinylpyrrolidone and vinyl pyrrolidone).

Neither Mehta nor Mulye teaches the mass fraction by dry weight of film-forming polymer (P1) relative to the total mass of the coating is between 40 and 90% and the mass fraction by dry weight of the water-soluble polymer (P2) P2/P1+P2 is between 15 and 60% relative to the total mass of the coating. In contrast Mehta merely teaches "at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of polymer in the microcapsule coating." *See*, Mehta at Col. 4, ll. 23 – 28.

A genus can only anticipate a species if one of ordinary skill in the art is able to "at once envisage" the species compound within the chemical formula of the genus compound. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962); see also *In re Meyer,* 599 F.2d 1026, 202 USPQ 175 (CCPA 1979) (A reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite."). Thus, the Examiner must show that one of ordinary skill in the art would be able to "at once envisage" the species ranges.

There is no evidence, however, that one viewing Mehta's "at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of polymer in the microcapsule coating" would envisage the species. The instant invention is to enhance and control release of a low solubility active principle whereas Mehta is to a different area of the pharmaceutical arts: that of masking taste by limiting the release of a highly soluble active principle with a disagreeable taste. There is no evidence that one of skill in the art would apply the teaching of Mehta to any field except taste masking, certainly not an art that would enhance solubility and make it more likely the active ingredient

would reach the taste buds and not mask the taste. Further, there is no evidence that one of ordinary skill in the art would take the very liberal genus of "at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of polymer in the microcapsule coating" and immediately envisage the specific species of P1 being between 40 and 90% and P2/(P1+P2) being between 15 and 60% relative to the total mass of the coating.

4) The vinyl pyrrolidone of Mehta is not the P2 polyvinyl pyrrolidone of the claims

The Examiner states that Mehta teaches plasticizers such as "polyvinyl pyrrolidone" in the coating, citing Mehta at Col. 5, ll. 41+. *See*, Office Action at page 4. Applicants note, however, with this Mehta citation teaches ***vinyl*** pyrrolidone, not ***polyvinyl*** pyrrolidone. Vinyl pyrrolidone is not the same compound as polyvinyl pyrrolidone.

Although polyvinyl pyrrolidone and vinyl pyrrolidone have related names, they have very different chemical structures, resulting in very distinct physical and chemical properties. For instance, polyvinylpyrrolidone is a solid and is a polymer, i.e. a macromolecule. *See*, Exhibit 1. In contrast, vinyl pyrrolidone is a liquid and a small molecule used as a plasticizer of polymers. See, Exhibit 2.

Thus, the vinyl pyrrolidone of Mehta has a different structure and chemical characteristics than the P2 polyvinyl pyrrolidone of the instant invention. Further, the one teaching in Mehta of using polyvinyl pyrrolidones states it may be "added to the core material." Mehta at Col. 8, ll. 3-13. In contrast, the instant invention teaches use of polyvinylpyrrolidones as a water soluble component (P2) of the coating. Thus, even this teaching cannot render the claims obvious.

5) The diluent of Mehta is not the solubilizing agent of the claimed invention

Applicant notes that the Examiner pulled ethyl cellulose from a laundry list, where ethyl cellulose is used as a *diluent* in the core, to state that Mehta teaches a diluent. Office Action at

page 4. This has no bearing on the present claims, because the invention is to use of ethyl cellulose as an element of the coating, and is not used in the core. Further, ethyl cellulose is not a solubilizing agent.

It appears the Examiner believes a diluent and a solubilizing agent are interchangeable. Applicant respectfully disagrees: a *diluent* is not the same as a *solubilizing agent*. Any substance that dilutes is a diluent. In contrast, a solubilizing agent makes more material dissolve in a given time or in a given volume.

Moreover, the solubilizing agent of the instant specification is described as "having the particularity, as soon as it is placed in aqueous solution at a concentration of 20% w/w at 37°C, of increasing the solubility of the AP by more than 50%." *See*, specification at ¶41. Indeed, the only solubilizing agents present in the instant specification are those selected from hydrophilic polymers, surfactants and sequestering agents. *See*, *Id.* at ¶55 – 63. Furthermore, solubilizing involves "mak[ing] a substance such as a fat or lipid soluble or more soluble, especially in water..." *See*, American Heritage® Dictionary of the English Language, 4th Edition, 2000. Indeed, the solubilizing agents of the instant specification are all substances that make fats or lipids more soluble in aqueous solutions, including hydrophilic polymers, surfactants, and sequestering agents.

In contrast, a diluent is "an inert substance used to dilute." *See*, *Id.*

There is no evidence that a diluent is a *prima facie* solubilizing agent, as suggested by the Examiner on page 3 of the Office Action. Further, as a common dictionary demonstrates, the characteristics of a solubilizing agent and a diluent are dissimilar.

Second, ethyl cellulose is not a solubilizing agent and would not increase the solubility of the active principle. In fact, as the instant specification and claims state, ethyl cellulose is water-insoluble. *See*, instant specification at ¶86, Claim 21. Moreover, the Applicant does not claim use of ethyl cellulose as solubilizing agent in the core. Instead, the Applicant has both discussed and claimed ethyl cellulose as a water-insoluble film forming polymer P1 of the coat. *Id.* As

such, the Examiner's reliance on Mehta has no bearing on the present claims, because the invention is to use of ethyl cellulose (not a solubilizing agent) as an element of the coating, and is not used in the core.

In addition, Applicant submits that the Examiner is picking and choosing from different portions of Mehta and adding the Examiner's own hindsight, which does not constitute anticipation, nor does it in any way demonstrate each element of the instant claims. Further, Applicant notes that for a reference to anticipate, the "elements must be arranged as required by the claim." *See*, MPEP 2131 (citing *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990)). Mehta, however, does not teach the elements arranged as required by the claim.

The instant specification also explains how to use the composition to form compounds with the desired properties: properties completely counter to those taught by Mehta. Mehta, in contrast to the Applicant's invention, has a laundry list of seven paragraphs of compounds that may be "high temperature film forming polymers." *See*, Mehta from Col. 4, l. 24 – Col. 5, l. 55. Applicant submits that although these compounds are named in the reference, there is no evidence that the compounds were actually prepared and have the properties of the instantly claimed dosage forms. The picking and choosing from the laundry list of compounds by the Examiner does not constitute anticipation.

6) One of skill in the art would not combine Mehta and Mulye because there references are non-analogous arts

One of skill would in no way combine Mehta with Mulye to form the claimed invention because these two references attempt to solve different problems. Indeed, one of skill in the art would find these references are nonanalogous art. To determine if two references are analogous, the court has found "the similarities and differences in structure and function of the inventions to carry far greater weight." *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973). Further, references which do not teach the same or similar problems are not analogous. See, MPEP 2141.01(a) citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed.

Cir. 1983). (To determine if analogous, court examined references to find if the references had the same and similar problems.). Mehta and Mulye are nonanalogous arts because their coatings have a different structure composition to serve different purposes. Their problems are in no way the same or similar.

Mulye, for example, uses a latex dispersion containing a polymer insoluble in acidic, basic and neutral pH. The problem that Mulye tries to solve is to control release of a drug by using a coating made out of an aqueous dispersion of polymers that gives low, continuous drug release. *See*, Mulye at Figure 1 – 3, abstract. Mulye goes through at great length to describe how others in the prior art attempt to use a rate controlling membrane surrounding a core to control drug release. See, *Id.* at Col. 1 – 4. Further, Mulye explains that his invention "is directed to a system for the controlled release of an active agent comprising a core and a coating [...] the coating comprising [...] an insoluble polymer [...] which is present in an aqueous latex dispersion". *Id.* at Col. 4 at Summary of the Invention. In contrast, Mehta uses high and low temperature polymers to form a coating over a drug. The problem that Mehta is trying to solve is to use a coat to hide taste. *See*, Mehta at Col. 1, ll. 5 – 7; Summary of Invention; Claim 1. Generally, Mehta is directed to a composition that masks taste so the drug, if chewed, does not produce a bitter taste. *See*, *Id.* at Col. 1, ll. 6 – 8. The purpose of making such a composition is to increase patient compliance, especially for children who may chew the pharmaceutical. *Id.* at Col. 1, ll. 32 – 46.

The purposes of (1) taste making, and (2) controlling drug release profiles using aqueous based coating compositions are dissimilar. In addition, the references did not have the same or similar problems. One reference had a problem of drug compliance based on drug taste, and the other reference had the problem of maintaining blood levels with a therapeutic range for an extended period of time while avoiding the use of organic solvents.

As such, one of skill in the art would not look to combine Mulye (coating to maintain blood levels) with Mehta (coating to mask taste) to cure one or more deficiencies with Mehta. The references do not teach the same or similar problem and have a different purpose. Thus, the references are nonanalogous art.

For this same reason, one of skill in the art would not look to use Mulye to cure any deficiencies for Mehta. As such, the obviousness rejection is in err, and Applicants request the rejection be withdrawn.

7) Even if one attempted to form the claimed invention from the cited references, there would be no expectation of success

Applicant submits that one of skill in the art would not have a reasonable expectation of success because Mehta is so vague and obtuse. For instance, Mehta is unclear which compounds are "high" or "low" temperature film forming polymers and how they are to be combined and/or used. For example, Mehta uses Eudragit E100 as an example of both a high and low temperature film-forming polymer. *See*, Mehta at Col. 5, l. 18, col.6, l. 6. Thus, according to Mehta, one compound can be both a high temperature and low temperature film-forming polymer. One with skill in the art would not have a reasonable expectation of success, because they would not know how to combine the vague and confusing Mehta with Mulye.

In addition, as explained above, Mehta neither teaches the claimed invention nor would be modified to teach the claimed invention. In both the text and the claims, Mehta uses functional language to make it clear that the invention is chewable and taste masking. *See, e.g.*, Claim 1. Given this express teaching of Mehta to mask taste and not be released- even in the mouth when chewing- it is unreasonable for the Examiner to take the position that the dry diluents of Mehta, which are used to reduce the concentration of the dry active ingredient in the Mehta compositions, are really used for solubilizing the ingredients. Such solubilization would make it more difficult to block the taste, which is the entire purpose of the Mehta teaching.

Mehta teaches coatings to mask taste, whereas Mulye teaches latex dispersion coats to control release of a drug. Mehta teaches microcapsules of 0.25 – 1mm in diameter, and Mulye doesn't teach a microcapsule of any diameter. Indeed, Mehta and Mulye are so distinct that the Examiner only relies on Mulye to teach use of a surfactant. There is no suggestion or motivation to modify or combine these references.

Further, one of skill would not combine Mehta and Mulye to solve a problem that is completely different from Mehta: controlling low solubility active principle release. See, ¶ 1 – 2. Control of the coating thickness and composition for an active principle of low solubility is difficult. If the coating is too thin, the film may not be even or difficult to reproduce. If the coating is too thick, the active principle drug release is slow or nonexistent. Applicants are credited with finding that the range of between about 3% and about 7% dry weight/dry weight of the microcapsule along with other claim limitations produces the desired effect. Mehta not only does not teach this range of coating, but instead teaches the substantially higher range of 20 – 40% by weight of the microcapsules and teaches away from the composition of the invention. Similarly, Mehta would not be concerned with hiding the taste of low solubility medicaments: they would not solubilize and would not lead to a bitter taste. *Id.*, Col. 1, l. 8.

A reference such as Mehta that teaches taste masking is fundamentally inconsistent with a product that increases solubility. The increase in solubility would make it more likely that the substance would reach and interact with the taste receptors of the tongue.

In addition, Applicants wish to clarify a few Examiner statements. For instant, the Examiner states that the Mehta "coating polymer is not soluble in the stomach as required in the instant claims." This, however, is contrary to the instant invention which requires polymer P2, which is water soluble. The Examiner also states that products of identical chemical compositions cannot have mutually exclusive properties. Applicants strongly disagree. Although this compound is not included in the claimed compositions, carbon helps to illustrate the fact that, to the contrary, the chemical formula of a compound is completely insufficient to describe its physicochemical properties: graphite and diamond have very different properties even though they have identical chemical formulas. Both graphite and diamond are pure carbon, but have distinct properties. Graphite is good electrical conductor, opaque to visible light, and a friable solid. In contrast, diamond that is a very good electrical insulator, transparent to visible light and a very hard solid. This fact is common to ***all*** chemical products: the properties of a chemical product depend not only on the chemical formula, but, sometimes more importantly, on the amount, the concentration, the location, the physical state, which itself is greatly dependent on

the manufacturing process, and also on the other components to which the chemical product may be intimately associated. In particular, in the present invention, the amount of solubilizing agent must be sufficient:

- to increase the solubility of the active principle by more than 50% in an aqueous solution and
- to confer properties upon the core such that in the dissolving test (TD) a non-coated core releases 80% of the active principle in less than 2 h.

Further, the amount of the coating constituents P1, P2, PL should be such that:

- the mass fraction by dry weight of P2/P1+P2 is between 15 and 60% relative to the total mass of the coating; and
- the mass fraction by dry weight of PL/P1+PL is between 1 and 30% relative to the total mass of the coating.

In conclusion, the combination of references does not teach or suggest all the claim limitations, there is no suggestion or motivation to combine because the references are non-analogous, and there is no reasonable expectation of success. As such, Applicants request the rejection be withdrawn. As Claims 17 and 19 – 31 contain the limitations from independent Claim 16, Applicants respectfully request that the rejection to Claims 16 – 17 and 19 – 31 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned. Should there be any outstanding matters that need to be resolved in the present application; the Examiner is respectfully requested to contact the telephone number of the undersigned below.

Applicants submit herewith a request for a two month extension of time and the corresponding fee. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account Number 50-2228, under Order No. 022290.0123PTUS, from which the undersigned is authorized to draw.

Dated: December 7, 2009

Respectfully submitted,

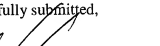
By 

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EXHIBIT 1

Responsible Party:	ISP Technologies Inc. 4501 Attwater Ave. and State Highway 146 Texas City, TX 77590
Emergency Telephone Number:	CHEMTREC: 1-800-424-9300 or 703-527-3887 (Outside of the USA) (Spill Related Emergencies) PROSAR: 1-800-241-7439 (Health Related Emergencies)
Prepared By:	Product Stewardship
Product Id:	72030I
Product Name:	PLASDONE® K-29/32
CAS Registry Number:	9003-39-8
CAS Name:	2-Pyrrolidinone, 1-ethenyl-, homopolymer
Formula:	$(C_6H_9NO)_x$
Synonyms:	PVP (INCI NAME)

Components:	Weight %	ACGIH Threshold Limit Values Data - Time Weighted Average (TWA):	OSHA Specifically Regulated Substances Data - Time Weighted Average (TWA):
2-Pyrrolidone 616-45-5	<3	No TLV/TWA Established	No TLV/TWA Established
2-Pyrrolidinone, 1-Ethenyl-, Homopolymer 9003-39-8	97	No TLV/TWA Established	No TLV/TWA Established

Statement of Hazardous Nature: Powdered material may form explosive dust-air mixtures.

Emergency Overview

POWDERED MATERIALS MAY FORM EXPLOSIVE DUST-AIR MIXTURES.

Hazard Overview

Target Organs:	None effected.
Primary Entry Routes:	Not applicable.
Acute Health Hazards:	None known.
Chronic Health Hazards:	None known

Signs and Symptoms of Overexposure

Eye Contact:	Not a hazard under normal use conditions.
Skin Contact:	Not a hazard under normal use conditions.
Ingestion:	Not a hazard under normal use conditions.
Inhalation:	Not a hazard under normal use conditions.

Eye Contact: Flush eyes with copious amounts of water.

Skin Contact:	Wash with soap and water.
Ingestion:	Do not induce vomiting. Slowly dilute with 1-2 glasses of water or milk and seek medical attention. Never give anything by mouth to an unconscious person.
Inhalation:	No specific treatment is necessary since material is not likely to be hazardous by inhalation. If exposed to excessive levels of dust or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

NFPA Rating:	Health: 1 Flammability: 0 Reactivity: 0
Flash Point (°F):	Not determined
Extinguishing Media:	All standard firefighting media
Unusual Fire/Explosion Hazards:	Powdered material may form explosive dust-air mixtures. Kst= 47 bar-m/sec - St-1 hazard class (NFPA 68)
Special Protective Equipment:	Fire fighters should wear full protective clothing, including self-contained breathing equipment.
HMIS RATING:	
HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

Personal Precautionary Measures:	Use appropriate protective equipment.
Procedure for Cleaning/Absorption:	Contain spill with sand or other inert materials.

Handling:	Avoid generating or breathing dust. Minimize dust generation and accumulation.
Storage:	Keep containers tightly closed when not in use. Store in a cool, dry place, out of direct sunlight.

Engineering Controls:	Use in a well ventilated area.
Respiratory Protection:	Use in a well ventilated area.
Hand Protection:	Use gloves as a standard industrial handling procedure.
Eye Protection:	Safety glasses.

Physical State:	Powder
Color:	Off white
Odor:	Not determined
Odor Threshold:	Not available
pH:	3.0-7.0 (5% solution)
Specific Gravity:	Not determined

Boiling Point (°F):	Not determined
Melting Point/Freezing Point(°F):	Not determined
Vapor Pressure:	Not determined
Solubility:	Soluble in Water

Chemical Stability:	Stable under normal conditions of handling, use and transportation.
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	Keep away from heat, sparks and flame. Minimize dust generation and accumulation.
Materials to Avoid:	Strong oxidizing agents. Strong reducing agents.
Hazardous Decomposition Products:	Oxides of nitrogen.

Toxicity Test:

Acute Oral LD50 (mg/kg):	>10,000
Sensitization:	Human RIPT: Non-sensitizing (as sold)
Mutagenicity:	Non-mutagenic. (Ames Assay; Dominant Lethal Test on mice; L5178Y Mouse (TK+/-) Lymphoma Assay; Bone Marrow Chromosomal Aberration Assay; BALB/C 3T3 Transformation)
Reproductive/Developmental Toxicity:	Various studies of the reproductive toxicity of PVP in rats and rabbits produced no evidence of embryo toxicity or teratogenicity.
Carcinogenicity:	Exposure of dogs and various rodent species to PVP via the diet, injection and implant at up to 10% produced no signs of carcinogenic activity. Exposure up to 10% in the diets of rats and dogs produced no signs of toxicity or carcinogenic potential.
Skin Irritation:	Non irritating (Human RIPT). (as sold)
Eye Irritation:	Non-irritating to rabbit eye (as sold).
Other Information:	Sub-Chronic Oral Toxicity: Exposure up to 10% in the diets of rats produced no signs of toxicity. Exposure up to 10% in the diet of dogs produced no signs of toxicity.

Biodegradability:	Readily Biodegradability: Not readily biodegradable (11% in 28 Days)
Aquatic Toxicity:	Juvenile Turbot: 96-hr. LC50 >1,000 mg/L Corophium Volutator; 10-Day LC50 >1,000 mg/L Marine Algae; 72-hr. EC50 >1,000 mg/L Salmon; PVP at up to 5% in the diet during smolt produced no signs of toxicity. Salmon; PVP at up to 5% in the diet for 112 days did not produce any signs of toxicity.

Disposal of Waste Method:	Federal, state and local disposal laws and regulations will determine the proper waste disposal/recycling/reclamation procedure. Disposal requirements are dependent on the hazard classification and will vary by location and the type of disposal selected.

Land Transportation:

DOT (Non-Bulk):

UN/NA Number:	NONE
DOT Shipping Name:	NOT REGULATED
Hazard Class:	NONE

DOT (Bulk):

UN/NA Number:	NONE
DOT Shipping Name:	NOT REGULATED

Air Transportation (IATA):

UN Number:	NONE
Proper Shipping Name:	NOT REGULATED
Hazard Classification:	NONE

Sea Transportation (IMO):

UN/ID Number:	NONE
Proper Shipping Name:	NOT REGULATED
Hazard Classification:	NONE

TDG (Canada):

Proper Shipping Name:	NOT REGULATED
Hazard Class:	NONE

TSCA Inventory List:	This product and/or its components is listed on TSCA.
California Proposition 65 Carcinogens & Reproductive Toxicity (CRT) List:	None of the components of this product is listed on CALPROP.
WHMIS Ingredient Disclosure List:	None of the components of this product is listed on WHMIS Ingredient Disclosure list.
Canada DSL Inventory List:	This product and/or its components is listed on DSL.
Canada NDSL Inventory List:	This product and/or its components is not listed on NDSL.

Japan Inventory of Existing & New Chemical Substances (ENCS):	This product and/or its components is listed on ENCS.
Australia Inventory of Chemical Substances (AICS) List:	This product and/or its components is listed on AICS.
EU EINECS List:	This product and/or its components is not listed on or is exempt from EINECS.
ELINCS:	This product and/or its components is not listed on ELINCS.

Prepared By:	Product Stewardship
Legend:	N.Av.= Not Available; N.Ap.= Not Applicable
Important Note:	For purposes of this MSDS, International Specialty Products, as responsible party, provides the information herein which is intended for use by persons who have or should obtain professional knowledge and experience in the subjects discussed. ISP's industrial products are used as materials in the production of products by industrial customers. ISP usually has only limited information about the products of its customers and their composition, methods of manufacture and use. Accordingly, ISP MAKES NO WARRANTY, EXPRESS OR IMPLIED, AS TO THE ACCURACY, COMPLETENESS OR RELIABILITY OF INFORMATION HEREIN EXCEPT THAT SUCH INFORMATION IS, TO THE BEST OF ISP'S KNOWLEDGE AND BELIEF, ACCURATE AS OF THE DATE INDICATED. ISP recommends that customers independently test and evaluate its products and their products and processes in which ISP products are used in order to decide their safety and effectiveness.

*****END OF MSDS*****

Identification of the substance/preparation

Product Id:	72030I
Product Name:	PLASDONE® K-29/32
CAS Registry Number:	9003-39-8
CAS Name:	2-Pyrrolidinone, 1-ethenyl-, homopolymer
Formula:	(C6H9NO)x
Responsible Party:	International Specialty Products 4501 Attwater Ave. and State Highway 146 Texas City, TX 77590 Distributed By: ISP (Great Britain) Co. Ltd. Waterfield, Tadworth Surrey KT20 5HQ, United Kingdom Tel: +44 1737 377 000
Synonyms:	PVP (INCI NAME)
Emergency Telephone Number:	+32.3.575.55.55 (SGS)
Prepared By:	Product Stewardship

Components:	Weight %	EU Classification:	German MAK:	UK OES/MEL:
2-Pyrrolidone 616-45-5	<3	Xi; R36/38	Not determined	Not determined
2-Pyrrolidinone, 1-Ethenyl-, Homopolymer 9003-39-8	97	Xi; R36/38	Not determined	Not determined

Hazard Overview

Target Organs: None.

Primary Entry Routes: Not applicable.

Acute Health Hazards: None known.

Chronic Health Hazards: None known

Signs and Symptoms of Overexposure

Eye Contact: Not a hazard under normal use conditions.

Skin Contact: Not a hazard under normal use conditions.

Ingestion: Not a hazard under normal use conditions.

Inhalation: Not a hazard under normal use conditions.

Eye Contact: Flush with copious amounts of water.

Skin Contact: Wash with soap and water.

Ingestion: Do not induce vomiting. Slowly dilute with 1-2 glasses of water or milk and seek medical attention. Never give anything by mouth to an unconscious person.

Inhalation: No specific treatment is necessary since material is not likely to be hazardous by inhalation. If exposed to excessive levels of dust or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

Flash Point (°F): Not determined

Extinguishing Media: All standard firefighting media

Unusual Fire/Explosion Hazards: Powdered material may form explosive dust-air mixtures. Kst= 47 bar-m/sec - St-1 hazard class (NFPA 68)

Special Protective Equipment: Fire fighters should wear full protective clothing, including self-contained breathing equipment.

Personal Precautionary Measures: Use appropriate protective equipment.

Procedure for Cleaning/Absorption: Contain spill with sand or other inert materials.

Handling: Avoid generating or breathing dust.
Minimize dust generation and accumulation.

Storage:	Keep containers tightly closed when not in use. Store in a cool, dry place, out of direct sunlight.

Engineering Controls:	Use in a well ventilated area.
Respiratory Protection:	Use in a well ventilated area.
Hand Protection:	Use gloves as a standard industrial handling procedure.
Eye Protection:	Safety glasses.

Physical State:	Powder
Color:	Off white
pH:	3.0-7.0 (5% solution)
Boiling Point (°F):	Not determined
Melting Point/Freezing Point(°F):	Not determined
Vapor Pressure:	Not determined
Solubility:	Soluble in Water

Chemical Stability:	Stable under normal conditions of handling, use and transportation.
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	Keep away from heat, sparks and flame. Minimize dust generation and accumulation.
Materials to Avoid:	Strong oxidizing agents. Strong reducing agents.
Hazardous Decomposition Products:	Oxides of nitrogen.

Toxicity Test:

Acute Oral LD50 (mg/kg):	>10,000
Sensitization:	Human RIPT: Non-sensitizing (as sold)
Mutagenicity:	Non-mutagenic. (Ames Assay; Dominant Lethal Test on mice; L5178Y Mouse (TK+/-) Lymphoma Assay; Bone Marrow Chromosomal Aberration Assay; BALB/C 3T3 Transformation)
Reproductive/Developmental Toxicity:	Various studies of the reproductive toxicity of PVP in rats and rabbits produced no evidence of embryo toxicity or teratogenicity.
Carcinogenicity:	Exposure of dogs and various rodent species to PVP via the diet, injection and implant at up to 10% produced no signs of carcinogenic activity. Exposure up to 10% in the diets of rats and dogs produced no signs of toxicity or carcinogenic potential.
Skin Irritation:	Non irritating (Human RIPT). (as sold)

Eye Irritation:	Non-irritating to rabbit eye (as sold).
Other Information:	Sub-Chronic Oral Toxicity: Exposure up to 10% in the diets of rats produced no signs of toxicity. Exposure up to 10% in the diet of dogs produced no signs of toxicity.

Biodegradability:	Readily Biodegradability: Not readily biodegradable (11% in 28 Days)
Aquatic Toxicity:	Juvenile Turbot: 96-hr. LC50 >1,000 mg/L Corophium Volutator; 10-Day LC50 >1,000 mg/L Marine Algae; 72-hr. EC50 >1,000 mg/L Salmon; PVP at up to 5% in the diet during smolt produced no signs of toxicity. Salmon; PVP at up to 5% in the diet for 112 days did not produce any signs of toxicity.

Disposal of Waste Method:	Follow all applicable community, national or regional regulations regarding waste management methods.

Land Transportation:	
DOT (Non-Bulk):	
UN/NA Number:	NONE
DOT Shipping Name:	NOT REGULATED
Hazard Class:	NONE
DOT (Bulk):	
UN/NA Number:	NONE
DOT Shipping Name:	NOT REGULATED
Air Transportation (IATA):	
UN Number:	NONE
Proper Shipping Name:	NOT REGULATED
Hazard Classification:	NONE
Sea Transportation (IMO):	
UN/ID Number:	NONE
Proper Shipping Name:	NOT REGULATED
Hazard Classification:	NONE
ADR:	
UN:	NONE
Proper Shipping Name:	NOT REGULATED
CLASS:	NONE

Classification:

This product is not classified as hazardous under the terms of the EEC directive 67/548/EEC, UN regulations or the European ADR/RID agreements.

TSCA Inventory List:	This product and/or its components is listed on TSCA.
California Proposition 65 Carcinogens & Reproductive Toxicity (CRT) List:	None of the components of this product is listed on CALPROP.
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Canada NDSL Inventory List:	This product and/or its components is not listed on NDSL.
EU EINECS List:	This product and/or its components is not listed on or is exempt from EINECS.
ELINCS:	This product and/or its components is not listed on ELINCS.
Germany VCI Assigned Classification into Water Endangering Classes (WGK) List:	This product and/or its components is listed on or has been reviewed by WGK.
Japan Inventory of Existing & New Chemical Substances (ENCS):	This product and/or its components is listed on ENCS.
Australia Inventory of Chemical Substances (AICS) List:	This product and/or its components is listed on AICS.

Prepared By:	Product Stewardship
Legend:	N.Av.= Not Available; N.Ap.= Not Applicable
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*****END OF MSDS*****

NONREGeurope

K-VALUE POVIDONE USP/Ph. Eur./J.P. K-30
POLYVINYLPYRROLIDONE

MSDS COVER SHEET

INTERNATIONAL SPECIALTY PRODUCTS
1361 ALPS RD.
WAYNE, NJ 07470

Trade Name: PLASDONE® K-29/32

Part Number: 72030I

CAS Registry Number: 9003-39-8

Toxicity Data - set up for copying product info.

For calculation purposes only

Eye Irritation-For calcualtion purposes(PII)

Skin Irritation-For calculation purposes(PII)

This product is currently not for sale in Europe.

TSCA Inventory List:	This product and/or its components is listed on TSCA.
California Proposition 65 Carcinogens & Reproductive Toxicity (CRT) List:	None of the components of this product is listed on CALPROP.
EU EINECS List:	This product and/or its components is not listed on or is exempt from EINECS.
ELINCS:	This product and/or its components is not listed on ELINCS.
Other Regulations:	This product is not classified as hazardous under the terms of the EEC directive 67/548/EEC, UN regulations or the European ADR/RID agreements.

Hazard Classification:	This product is non-hazardous, and no special precautions require to be taken in connection with transportation.

ISP

Safety Data Sheet (91/155/EEC)
72030I

Revision Date: 06/27/2006
Issued: 06/27/2006

PLASDONE® K-29/32

EXHIBIT 2

BASF
The Chemical Company

Safety data sheet
N-Vinyl-2-pyrrolidone non-stab.

Revision date : 2008/12/17
Version: 2.0

1. Substance/preparation and company identification

Company
BASF CORPORATION
100 Campus Drive
Florham Park, NJ 07932, USA

24 Hour Emergency Response Information
CHEMTREC: 1-800-424-9300
BASF HOTLINE: 1-800-832-HELP

Molecular formula: C(6)H(9)NO
Chemical family: unspecified, amine
Synonyms: 1-ETHENYL-2-PYRROLIDINONE

2. Composition/information on ingredients

CAS Number	Content (W/W)	Chemical name
88-12-0	> 99.0 %	1-vinyl-2-pyrrolidone
616-45-5	<= 0.2 %	2-Pyrrolidone

3. Hazard identification

Emergency overview

WARNING: Causes eye irritation.
MAY CAUSE SKIN IRRITATION.
MAY BE HARMFUL IF SWALLOWED.
HARMFUL IF INHALED.
Use with local exhaust ventilation.
Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator.
Wear NIOSH-certified chemical goggles.
Wear protective clothing.
Eye wash fountains and safety showers must be easily accessible.
Wear full face shield if splashing hazard exists.

Potential health effects

Primary routes of exposure
Routes of entry for solids and liquids include eye and skin contact, ingestion and inhalation. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquified gases.

Acute toxicity:
Of moderate toxicity after short-term inhalation. Of moderate toxicity after short-term skin contact. Of moderate toxicity after single ingestion.

Irritation:
May be irritating to the airways. May cause severe damage to the eyes.

Sensitization:

Skin sensitizing effects were not observed in animal studies.

Repeated dose toxicity:
The substance may cause a specific damage to organs through repeated inhalative exposure.
Information on: N-Vinyl Pyrrolidone
Rats exhibited minor liver changes at airborne levels of 15 ppm and irritation of the nasal mucosa at 5 ppm. The results of a two year inhalation study indicate that rats exposed to 5, 10 and 20 ppm NVP exhibited benign or malignant tumors of the nasal tissues. Only benign tumors were observed among females at 10 ppm and males and females at5 ppm. Liver damage was noted at all dose levels, including a significant increase in the occurrence of malignant tumors in the livers of the high dose animals. Tumors of the larynx were also observed among the animals at the highest dose.
Information on: N-Vinyl Pyrrolidone (NVP)
N-vinylpyrrolidone is moderately toxic by ingestion and may be absorbed via skin or inhalation. Acute and subchronic animal studies indicate that overexposure to NVP by ingestion or inhalation may result in liver and kidney injury.
Information on: N-Vinyl Pyrrolidone (NVP)
In a screening study, liver tumors were reported in male mice administered a single intraperitoneal injection of NVP and allowed to mature to the age of 10 months.

Medical conditions aggravated by overexposure:
Data available do not indicate that there are medical conditions that are generally recognized as being aggravated by exposure to this substance/product.
See MSDS section 11 - Toxicological information.

Potential environmental effects

Aquatic toxicity:
Acutely harmful for aquatic organisms.
The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

4. First-aid measures

General advice:
Remove contaminated clothing.

If inhaled:
Remove the affected individual into fresh air and keep the person calm. Assist in breathing if necessary. Immediate medical attention required.

If on skin:
Wash affected areas thoroughly with soap and water. Remove contaminated clothing. Wash soiled clothing immediately. If irritation develops, seek medical attention.

If in eyes:
In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. If irritation develops, seek medical attention. Immediate medical attention required.

If swallowed:
Rinse mouth and then drink plenty of water. Induce vomiting. Never induce vomiting or give anything by mouth if the victim is unconscious or having convulsions. Immediate medical attention required.

5. Fire-fighting measures

Flash point:	95 °C	(DIN 51758)
Autoignition:	240 °C	(DIN 51794)
Lower explosion limit:	1.4 %(V)	
Upper explosion limit:	10.0 %(V)	
Flammability:	not readily ignited	

Suitable extinguishing media:
water fog, foam, dry extinguishing media

Hazards during fire-fighting:
nitrogen oxides
See MSDS section 10 - Stability and reactivity.

Protective equipment for fire-fighting:
Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.

Further information:
Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems.

NFPA Hazard codes:
Health : 2 Fire: 1 Reactivity: 0 Special:

6. Accidental release measures

Personal precautions:
Wear appropriate respiratory protection. Use personal protective clothing. Ensure adequate ventilation.

Environmental precautions:
Do not empty into drains.

Do not discharge into drains/surface waters/groundwater. This product is not regulated by RCRA.

Cleanup:

For large amounts: Pump off product.
For residues: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr). Dispose of absorbed material in accordance with regulations.

7. Handling and storage

Handling

General advice:
Ensure thorough ventilation of stores and work areas. Protect against heat. Product solidified and/or tending to sedimentation in barrels can be liquified or homogenized by careful application of indirect heat (no naked flames or direct contact with a heat source). Homogenize before use.

See MSDS section 10 - Stability and reactivity. See MSDS section 5 - Fire fighting measures.

Protection against fire and explosion:
Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy. Heated containers should be cooled to prevent polymerization.

Storage

General advice:
Keep only in the original container.

Storage incompatibility:
General: Segregate from acids and acid forming substances.

Storage stability:
Storage temperature: 17 - 23 °C
Storage duration: 14 d
May yellow after lengthy storage.

Temperature tolerance
Protect from temperatures above: 25 °C
Changes in the properties of the product may occur if substance/product is stored above indicated temperature for extended periods of time.

8. Exposure controls and personal protection

Components with workplace control parameters

1-vinyl-2-pyrrolidone

ACGIH	TWA value	0.05 ppm ;

Advice on system design:
Provide local exhaust ventilation to control vapours/mists.

Personal protective equipment

Respiratory protection:
Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator. Do not exceed the maximum use concentration for the respirator facepiece/cartridge combination. For emergency or non-routine, high exposure situations, use a NIOSH-certified full facepiece pressure demand self-contained breathing apparatus (SCBA) or a full facepiece pressure demand supplied-air respirator (SAR) with escape provisions.

Hand protection:
Chemical resistant protective gloves

Eye protection:
Tightly fitting safety goggles (chemical goggles). Wear face shield if splashing hazard exists.

General safety and hygiene measures:
Wear protective clothing as necessary to prevent contact. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Form:	liquid	
Odour:	odourless, amine-like	
Colour:	colourless to yellowish	
pH value:	9 - 10	(100 g/l, 20 °C)
melting range:	13 - 14 °C	
Boiling range:	90 - 92 °C	(13 mbar)
Vapour pressure:	0.12 mbar	(20 °C)
	1.23 mbar	(50 °C)
Density:	1.043 g/cm3	(20 °C)
Partitioning coefficient n-octanol/water (log Pow):	0.4	(25 °C)
Viscosity, dynamic:	2.4 mPa.s	(20 °C)
Solubility in water:		(20 °C) miscible
Miscibility with water:		(20 °C) miscible in all proportions
Solubility (qualitative):	miscible solvent(s): organic solvents,	

10. Stability and reactivity

Conditions to avoid:
No conditions known that should be avoided.

Substances to avoid:
free radical initiators, acids, oxidizing agents, peroxides

Hazardous reactions:
Heat develops during polymerization. The product can polymerize if the shelf life or storage temperature are greatly exceeded.
Reacts with oxidizing agents.

Corrosion to metals:
No corrosive effect on metal.

11. Toxicological information

Acute toxicity

Oral:
LD50/rat: 1,022 mg/kg (BASF-Test)

Inhalation:
LC50/rat: 3.07 mg/l / 4 h(BASF-Test)

rat: / 8 h(IRT)
No mortality within the stated exposition time as shown in animal studies.

Dermal:
LD50/rabbit: > 400 mg/kg (BASF-Test)
No mortality was observed.

Skin irritation:
rabbit: non-irritant (BASF-Test)

eye irritation :
rabbit: irritant. (Draize test)
The European Union (EU) has classified this substance with 'Risk of serious damage to eyes' (R41)

Sensitization:
Buehler test/guinea pig: Non-sensitizing. (OECD Guideline 406)

Chronic toxicity

Genetic toxicity:
The substance was not mutagenic in bacteria.
The substance was not mutagenic in mammalian cell culture.
The substance was not mutagenic in a test with mammals.

Carcinogenicity:
Indication of possible carcinogenic effect in animal tests.

Reproductive toxicity:
The results of animal studies gave no indication of a fertility impairing effect.

The results of animal studies suggest a fertility impairing effect.

12. Ecological information

Environmental fate and transport

Biodegradation:
Test method: OECD 301 A (new version) (aerobic), activated sludge, domestic
Method of analysis: DOC reduction
Degree of elimination: 90 - 100 % (28 d)
Evaluation: Readily biodegradable (according to OECD criteria).

Bioaccumulation:

Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is not to be expected.

Adsorbable organically-bound halogen (AOX):

This product contains no organically-bound halogen.

Environmental toxicity

Acute and prolonged toxicity to fish:
OECD Guideline 203 static
trout, rainbow/LC50 (96 h): 913 mg/l
The details of the toxic effect relate to the nominal concentration.

Acute toxicity to aquatic invertebrates:
OECD Guideline 202, part 1 Daphnia magna/EC50 (48 h): 45 mg/l
The details of the toxic effect relate to the nominal concentration.

Toxicity to aquatic plants:
DIN 38412 Part 9 green algae/EC50 (72 h): > 1,000 mg/l
The details of the toxic effect relate to the nominal concentration.

Toxicity to microorganisms:
DIN 38412 Part 8 bacterium/EC50 (17 h): 4,812 mg/l
The details of the toxic effect relate to the nominal concentration.
OECD Guideline 209 aquatic
activated sludge, industrial/EC20 (30 min): > 1,995 mg/l

13. Disposal considerations

Waste disposal of substance:
Dispose of in accordance with national, state and local regulations.
Incinerate or dispose of in a licensed facility.

Container disposal:
Packs must be completely emptied.

14. Transport information

Land transport
USDOT

Hazard class:	6.1
Packing group:	III
ID number:	UN 2810
Hazard label:	6.1
Proper shipping name:	TOXIC LIQUID, ORGANIC, N.O.S. (contains 1-VINYL-2-PYRROLIDONE)

Sea transport
IMDG

Hazard class:	6.1
Packing group:	III
ID number:	UN 2810
Hazard label:	6.1
Marine pollutant:	NO
Proper shipping name:	TOXIC LIQUID, ORGANIC, N.O.S. (contains 1-VINYL-2-PYRROLIDONE)

Air transport
IATA/ICAO

Hazard class:	6.1
Packing group:	III
ID number:	UN 2810
Hazard label:	6.1
Proper shipping name:	TOXIC LIQUID, ORGANIC, N.O.S. (contains 1-VINYL-2-PYRROLIDONE)

15. Regulatory information

Federal Regulations

Registration status:
TSCA, US released / listed

OSHA hazard category: Skin and/or eye irritant, Other carcinogen, Chronic target organ effects reported, Acute target organ effects reported

SARA hazard categories (EPCRA 311/312): Chronic, Acute

State regulations

State RTK

CAS Number	Chemical name	State RTK
616-45-5	2-Pyrrolidone	MA, PA

16. Other information

HMIS III rating
Health: 2* Flammability: 1 Physical hazard: 0

HMIS uses a numbering scale ranging from 0 to 4 to indicate the degree of hazard. A value of zero means that the substance possesses essentially no hazard; a rating of four indicates high hazard.

Local contact information
prod_reg@basf.com

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